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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,035	05/28/2002	Gregory J. Hannon	GNCA-P01-005	9270

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EXAMINER	
TON, THAIAN N	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 12/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,035	HANNON ET AL.	
	Examiner	Art Unit	
	Thaian N. Ton	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) *21, 22, 31-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20, 23-30 and 37-48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-48 are pending. Claims 21, 22, 31-36 are improper multiple dependent claims and are withdrawn. Claims 1-20, 23-30 and 37-48 are under current consideration for restriction purposes.

Claims 41 and 42 are identical. Appropriate correction is required.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 5-8, 13-20, 23-30, 45, drawn to a method for increasing the proliferative capacity of cells comprising contacting the cell with a first agent which reversibly activates telomerase activity in the cell, and a second agent which reversibly inactivates the Rb/INK4 pathway.

Group II, claim(s) 1, 5-8, 13-20, 23-30, 45, drawn to method for increasing the proliferative capacity of cells comprising contacting the cell with a first agent which reversibly activates telomerase activity in the cell, and a second agent which reversibly inactivates the p53 pathway.

Group III, claim(s) 2, 23-30, drawn to for increasing the proliferative capacity of cells comprising contacting the cell with a first agent which reversibly activates telomerase activity in the cell, and a second agent which reversibly inactivates a ras pathway.

Group IV, claim(s) 3, 23-30, drawn to a method for increasing the proliferative capacity of cells comprising contacting the cell with an agent which decreases Rb-dependent cellular senescence.

Group V, claim(s) 4, 23-30, drawn to a method for increasing the proliferative capacity of cells, comprising contacting the cell with an agent which decreases ras-dpeendent cellular senescence.

Group VI, claim(s) 1, 9-12, drawn to a method for increasing the proliferative capacity of cells comprising contacting the cell with a first agent which reversibly activates telomerase activity in the cell, and a second agent which reversibly inactivates the Rb/INK4 pathway, wherein the method further comprises contacting the cell with an agent that inhibits a ras-dependent replicative senescence.

Group VII, claim(s) 1, 9-12, drawn to a method for increasing the proliferative capacity of cells comprising contacting the cell with a first agent which reversibly activates telomerase activity in the cell, and a second agent which reversibly inactivates the p53 pathway, wherein the method further comprises contacting the cell with an agent that inhibits a ras-dependent replicative senescence.

Group VIII, claim(s) 37-44, 46 and 47 drawn to a medicament, cosmetic preparation and kit formulated for increasing the proliferative capacity of cells comprising an agent which reversibly activates telomerase activity in the cell, and an agent which reversibly activates an Rb/INK4 pathway and a method of *ex vivo* therapy.

Group IX, claim(s) 37-44, 46 and 47 drawn to a medicament, cosmetic preparation and kit formulated for increasing the proliferative capacity of cells comprising an agent which reversibly activates telomerase activity in the cell, and an agent which reversibly activates a p53 pathway and a method of *ex vivo* therapy.

Group X, claim(s) 48, drawn to a method for cloning a mammal.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Unity of Invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:

1) A product and a special process of manufacture of said product
2) A product and a process of use of said product

3) A product, a special process of manufacture of said product, and a process of use of said product

4) A process and an apparatus specially designed to carry out said process

5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products as claimed in the instant invention.

37 CFR 1.475 (c) states that:
"If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.475 (d) states:
"If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c)."

37 CFR 1.475(e) states:
"The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim."

Rule 13.1 PCT states that for unity of invention to be present, all subject matter should be linked by a single general inventive concept. In the present application, various methods are described. Specifically, claims 1 to 4 describe methods for increasing the proliferative capacity of cells, comprising:

treatment of a cell with an agent reversibly activating telomerase activity, and an agent reversibly inactivating a p53, or an Rb/lNK4 pathway (claim l);

treatment of a cell with an agent reversibly activating telomerase activity, and an agent reversibly inactivating a Ras pathway (claim 2).,

treatment of a cell with an agent decreasing Rb-dependent cellular senescence (claim 3),

treatment of a cell with an agent decreasing Ras-dependent cellular senescence (claim 4).

The technical feature common to these methods is that they increase the proliferative capacity of cells. This, however, is not novel, since methods to "increase the proliferative capacity of cells" are widely known in the art, e.g., transformation with certain viruses, or specific factors such as the SV40 large T antigen, etc. (see also description, pg. 6, lines 13-18). Therefore, the linking concept to the presented genes and proteins cannot be regarded as novel and inventive.

Thus, in view of the above, the instant invention is found to lack unity. Groups I-X are drawn to different methods, which each have different modes of operation, functions, and technical considerations. Furthermore, any one method is not required for the implementation of the other, and each of the methods requires a materially different and separate protocol. The inventions of Groups I-X do not relate to a single inventive concept.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1. The second agent (as recited in claims 5, 7, 8)

   a) MDM2 or a fragment thereof
   b) a dominant negative cdk4 or cdk6 mutant
   c) a dominant negative Rb mutant
   d) a papillomavirus E7 protein or other viral oncoprotein which bypasses Rb and/or p53 or a fragment thereof
   e) a cyclin
   f) a transcriptional repressor
   g) a dominant negative mutant of a transcriptional activator which inhibits expression of Rb, an INK4 protein other positive regulator of Rb antiproliferative activity
   h) an antisense molecule
   i) a small molecule inhibitor of Rb or p16 function

The agents are distinct because they are distinct in chemical structure and function, as well as modes of operation. Therefore, it would be an undue burden on the examiner to search all of the above-listed agents.

2. Agent (as recited in claims 10-12)

   a) an inhibitor of a ras/Raf/MKK/MAP kinase pathway
   b) an inhibitor of prenylation of ras
   c) a dominant negative ras mutant
   d) an antisense inhibitor of ras expression
   e) other genetic suppressor elements of ras
   f) a Rap1 protein or fragment thereof

The agents are distinct because they are distinct in chemical structure and function, as well as modes of operation. Therefore, it would be an undue burden on the examiner to search all of the above-listed agents.

3. The First Agent (as recited in claims 13-18)

a) an expression construct encoding an EST2 polypeptide or other telomerase activator
b) an agent which increases or activates expression of an endogenous EST2 gene
c) a telomerase activator polypeptide formulated for transcellular uptake
d) an agent which inhibits inactivation of endogenous EST2 protein
e) an agent which inhibits inactivation of endogenous *myc* protein
f) an agent that derepresses *myc*
g) an EST2 polypeptide that is identical to or homologous to SEQ ID NO: 2
f) a nucleic acid which encodes EST2 polypeptide and hybridizes under stringent conditions to SEQ ID NO:1
g) an RNA agent that encodes the telomerase activator
h) an agent which inhibits inactivation of an endogenous EST2 protein by inhibiting post-translational modification of the protein
i) an agent which inhibits inactivation of an endogenous myc protein by inhibiting post-translational modification of the protein
j) an agent which inhibits inactivation of an endogenous EST2 by inhibiting ubiquitin-mediated degradation of the protein
k) an agent which inhibits inactivation of an endogenous myc protein by inhibiting ubiquitin-mediated degradation of the protein
l) an agent which depresses mad-dependent antagonism of myc

The agents are distinct because they are distinct in chemical structure and function, as well as modes of operation. Therefore, it would be an undue burden on the examiner to search all of the above-listed agents.

4) Contacting of cell (as recited in claim 24)

a) in culture
b) *ex vivo* explant

The modes of contacting cells are distinct in technical considerations, and therapeutic considerations, with regard to *ex vivo* explant. Thus, it would be an undue burden on the examiner to search the above-recited modes of contacting cells.

5) Cell type (as recited in claims 27-30)
   a) neuronal
   b) hematopoietic
   c) pancreatic
   d) hepatic
   e) epithelial
   f) mesenchymal
   g) chondrocyte
   h) osteocyte

Each of the above-recited cell types are distinct in structure, function and require different technical considerations. Therefore, it would be an undue burden on the examiner to search all of the above-listed cell types.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1-4, 26.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the agents, cell types and modes of contacting the cells are different structurally and/or functionally, as well require different technical and therapeutic considerations.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the Examiner be unavailable, inquiries should be directed to Amy Nelson, Acting SPE of Art Unit 1632, at (571) 272-0804. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

tnt
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